The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MATTHEW JOSEPH DOYLE, STEPHEN JOSEPH HUNTER-RINDERLE, and ROBERT ERNEST SINGER, JR.

Appeal No. 2006-0197
Application No. 09/607,602

MAILED
MAR 31 2006
U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

Before ADAMS, MILLS and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of promoting whole body health in humans and animals, which the examiner has rejected as anticipated by the prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm.

Background

The specification discloses that the present invention relates to a method of "promoting and/or enhancing whole body health or overall systemic health in humans and other animals, by use of topical oral compositions comprising one or a mixture of host-response modulating agents, which are particularly effective in mediating host reaction to the presence of periodontal pathogens in the oral cavity." Specification,

page 1, lines 8-13. In a preferred embodiment, the host-response modulating agent is an H2-antagonist. Specification, page 7, lines 17-18. One such H2-antagonist is "cimetidine." Specification, page 13, line 10. The safe and effective amount of the host-response modulating agent is the amount necessary "to provide the desired benefit while being safe to the hard and soft tissues of the oral cavity...[and] will vary with the particular condition being treated, the age and physical condition of the patient..., the duration of treatment, the nature of concurrent therapy, the specific form of host-response modulating agent employed, and the particular vehicle from which the...agent ion is applied." Specification, page 8, lines 17-23. The preferable pharmaceutically acceptable carriers "can include the usual and conventional components of toothpastes (including gels and gels for subgingival application), mouth rinses, mouth sprays, dental solutions including irrigation fluids, chewing gums, and lozenges (including breath mints)." Specification, page 27, lines 30-33.

The specification states that the invention is important because "periodontal disease (gum disease) may be a far more serious threat to overall systemic health than previously realized. Periodontitis, a form of periodontal disease, is a tissue destructive process resulting from the accumulation of pathogenic bacteria along the gingival margin and the consequent tissue destructive host response to these pathogens. The presence of periodontitis can result in the release of bacteria and/or bacterial toxins into the bloodstream...[and] may contribute to the development of atherosclerosis (heart disease), increase the risk of premature, underweight babies; and pose a serious threat to people whose health is compromised by diabetes, severe respiratory diseases, stroke and bacteremia (bacteria in the blood.)" Specification, page 1, lines 20-30.

DISCUSSION

1. Claim construction

Claims 2-4 and 7 are pending. Since Appellants have not argued the claims separately, they will stand or fall together. See 37 CFR 41.37(c)(1)(vii). We will focus on independent claim 2 as the representative claim, which reads:

> 2. A method for promoting whole body health in human and other animal subjects comprising
>
> topically administering to said subjects' oral cavity a topical oral composition comprising a safe and effective amount of a host-response modulating agent and a pharmaceutically acceptable oral carrier,
>
> wherein said host-response modulating agent is a H2-antagonist.

Thus, claim 2 is directed to a method of topically administering a topical oral composition comprising a host-response modulating agent, e.g., an H2-antagonist, such as cimetidine, and a pharmaceutically acceptable oral carrier, e.g., toothpaste or mouthwash, to a subjects' oral cavity to promote whole body health in human and animal subjects. See specification, page 27. According to the specification, page 8, a "topical oral composition" is a "product which in the ordinary course of usage is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity."

2. Anticipation

The examiner rejected claims 2-4 and 7 under 35 U.S.C. § 102(b) as being anticipated by Pan.[1] The examiner rejected claims 2-4 and 7 under 35 U.S.C. § 102(b)

[1] Pan et al., WO 97/16159, published May 9, 1997.

as being anticipated by Singer.[2] The examiner also rejected claims 2 under 35 U.S.C. § 102(b) as being anticipated by Tsujita.[3]

It is well known that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or *inherently* described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added).

According to the examiner (Answer, pages 3-5),

> Pan et al teaches that histamine H-2 receptor antagonists including cimetidine may be employed in an oral composition in an amount effective to treat or prevent inflammation in the oral cavity said composition may also comprise essential oils to act as antimicrobial agents...
>
> [Singer] teaches a method for treatment and prevention of gingivitis or periodontitis comprising the topical administration of the oral cavity of a composition comprising a histamine-[2] receptor antagonist compound in the form of a dentifrice, mouthwash, mouth rinse, mouth spray, or dental treatment solution...a toothpaste, tooth gels, tooth powders, chewing gum...
>
> Tsujita et al teaches a method of treating the oral cavity disease of gingivitis comprising cimetidine [an H2 antagonist] as an active ingredient...

In addition, Pan teaches that the inflammatory conditions treated by its method include "gingivitis and periodontitis." Pan, page 3, line 15. The safe and effective amount to treat such inflammations are "preferably in an amount of from about 0.01% to about 5%, and most preferably from about 0.025% to about 0.3% by weight, based on the total weight of the oral composition." Page 4, lines 4-8. Pan also teaches that the composition for oral administration includes "toothpaste, tooth gels, tooth powders, mouthwashes, mouthsprays, and the like." Page 13, lines 20-23. With regard to Singer, the safe and effective amounts vary according to the type of composition. Singer, column 19, line 25 – column 21, line 3. Regarding the safe and effective amounts of the H2-antagonist, Tsujita teaches that "[a]ntagonists at the level of at 100 μg/ml" could

---

[2] Singer et al., U.S. Patent No. 5,364,616, issued November 15, 1994.
[3] Tsujita et al., JP 04089428A, published March 23, 1992.

provide the needed phagocytic function. Page 6.

For each of the cited references, it is the examiner's position that "whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." Answer, pages 3-5 (emphasis added). We agree with the examiner that the disclosed methods in each of the cited references meet all the limitations of claim 2.

"[A]fter the [examiner] establishes a prima facie case of anticipation based on inherency, the burden shifts to appellant to 'prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986) (quoting In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971)).

Appellants argue in rebuttal that the anticipatory rejections discussed above are "improper, because none of the citations discloses all the material elements of the claims. Specifically there is no disclosure whatsoever in any of the citations of the 'new use' of the present method, i.e., promoting whole body health or systemic health." Brief, page 6. Appellants argue that "the ONLY USES disclosed are for treatment of gingivitis or periodontitis." Brief, page 7. Thus, Appellants' take the position that: "There is no disclosure nor any suggestion whatsoever in any of the cited art with regard to promoting systemic or whole body health much less that such systemic benefit would be provided by topically administering the present H2-antagonist containing compositions." Brief, page 7.

This argument, however, is not persuasive. As discussed herein, each of the prior art references teach an H2-antagonist that is topically administered to treat periodontitis or gingivitis at an oral cavity. Additionally, the broad method steps claimed in the instant application are the same steps disclosed in the prior art. According to the examiner, "[t]he old process is indistinguishable from the presently recited claims in

either the patients treated, active agents used or mode of administration and/or dosage amounts used." Examiner's Answer, page 6. Specifically, the H2-antagonist is administered to the same subject population, e.g., those with gum disease such as gingivitis and/or periodontitis, in a similar effective amount as recited in Appellants' specification and claims. As such, the method would inherently result in whole body health, even if that effect was not recognized. Thus, stating a new benefit of the known method of topically administering H2-antagonist does not distinguish the claimed method of promoting whole body health from the inherent anticipation of the prior art.[4] Appellants do not distinguish the steps of the claimed method of promoting whole body health from the steps of the prior art methods of topically administering in the oral cavity and H2-antagonist.

Appellants further argue that the case law cited by examiner[5] is not applicable to the instant invention because "the present use of promoting systemic or whole body health is new and different use from the prior disclosed use of treating nonsystemic or localized conditions of dental plaque, gingivitis and periodontitis." See Brief, pages 8-11. In particular, appellants argue that, In re Marshall, 578 F.2d 301, 198 USPQ 344 (CCPA 1978), stands for the legal proposition that "[a]n accidental or unwitting duplication of any invention may not constitute an anticipation." Reply Brief, page 6. Therefore, appellants allege that "such a conclusion of inherency is based upon improper hindsight reasoning." Reply Brief, page 8.

---

[4] It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 919 F.2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990).

[5] In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); Bird Provision Co. v. Owens Country Sausage, Inc., 568 F.2d 369, 375, 197 USPQ2d 134, 139 (5th Cir. 1978); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1379, 58 USPQ2d 1508, 1516 (Fed. Cir. 2001); In re Shetty, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977).

This argument is also unconvincing. The facts and prior art of this case are distinguishable from those Marshall. Pan, Singer, and Tsujita and the instant specification are both directed to the same subject population and same tissue, e.g., administering H2-antagonist in patients with gum disease. In Marshall, the claims were directed to a weight control process and the cited reference was directed to treatment of esophagitis, gastritis, peptic ulcer and irritable colon syndrome, and the anesthetic release of gastrin, reflecting different patient populations. Reply Brief, pages 6.

Even assuming, arguendo, that appellants were the first discover that topically administering H2-antagonist to treat whole body health, it is well settled that "merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376, 58 USPQ2d 1508, 1514 (Fed. Cir. 2001). In view of the above appellants have failed to provide and establish sufficient evidence to distinguish the method of claim 2 from methods disclosed by Pan, Singer, and Tsujita. Thus, we agree with the examiner that each of the prior art reference cited is anticipatory and affirm the rejection of claim 2 for anticipation over Pan, Singer, and Tsujita. Claims 3-4 and 7 fall with claim 2.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Donald E. Adams
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Lora Green
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

THE PROCTER AND GAMBLE COMPANY
Intellectual Property Division
Winton Hill Technical Center, Box 161
6110 Center Hill Avenue
Cincinnati, OH 45224